Department of Defense
Health Care Provider's
Briefing

# SMALLPOX

7 July 04

# Purpose

- To prepare health-care providers to understand smallpox vaccination

- Refer to DoD Smallpox Response Plan (www.smallpox.mil/resource/SMAplan/SMAplan.asp) for information about:
  - Surveillance for fever-rash illness
  - Epidemiologic response (contact tracing)
  - Other smallpox issues

# Key Messages

1. Smallpox would disrupt military missions, because it is contagious and deadly
2. Smallpox vaccine prevents smallpox, but requires very careful use
3. Preserving the health and safety of our people are our top concerns
4. Smallpox protection helps our War on Terrorism: New threats require new measures of force protection

# Threat

***Smallpox would disrupt military missions, because it is contagious and deadly***

- **Smallpox is a contagious disease that spreads from one person to another**
- **Before smallpox was eradicated, it killed many millions of people over hundreds of years**
- **Terrorists or governments hostile to US may have or could obtain variola virus**
- **A smallpox outbreak would significantly affect military readiness**

# Smallpox

## Threat to Fighting Forces

- A smallpox outbreak would significantly degrade combat mission capability, because almost all troops are susceptible
- An outbreak could restrict movement of troops, aircraft, ships
- Smallpox would stress medical operations to maximum capacity

# Epidemiology of Smallpox

- Smallpox was once worldwide in scope and was declared eradicated from the Earth in 1980
- Smallpox spreads primarily by prolonged (> 1 h) face-to-face contact

  ~ 15 days between generations of smallpox cases.
- Smallpox cases infected 3 to 5 other people (average), 58% of household contacts
- A smallpox patient is most infectious from onset of rash, marked by temperature > 101°F (38.8°C)
- As scabs form, infectivity decreases rapidly.

There were two primary forms of the disease:

- Variola major: 30% lethality
- Variola minor (alastrim): 1% lethality

# Pathogenesis

- Natural infection occurs after virus implants on oropharyngeal, respiratory mucosa
- Infectious dose unknown, but believed to be only a few virions
- Virus migrates and multiplies in regional lymph nodes
- Symptomatic viremia develops on day 3 or 4
- Secondary viremia begins on 8$^{th}$ day, followed by fever & toxemia
- Virus localizes in small blood vessels of dermis and infects adjacent cells

# *Smallpox Infection Timeline*

Post-exposure vaccination fully or partially protective through day 3 after exposure.

Average smallpox case infects 3 to 5 people. About half of close contacts are infected.

First symptoms develop 7 to 17 days after exposure; average depicted here as day 11.

After symptoms develop, isolate case. Trace and vaccinate contacts.

| Communic-ability | Exposure = Day 0 | Symptoms | Day of Symptoms | Disease Progress |
|---|---|---|---|---|
| Not contagious | Day 1 | No symptoms | | Virus introduced to respiratory tract |
| | 2 | | | |
| | 3 | | | |
| | 4 | | | Virus appears in lymph nodes |
| | 5 | | | |
| | 6 | | | Virus replicates in lymph system |
| | 7 | | | |
| | 8 | | | |
| | 9 | | | |
| | 10 | | | |
| | 11 | First symptoms | Day 1 | |
| | 12 | | 2 | Fever, backache, headache, nausea, malaise |
| Contagious | 13 | | 3 | |
| | 14 | | 4 | |
| | 15 | Rash | 5 | Macules (spots) |
| Very contagious | 16 | | 6 | Papules (bumps, pimples) |
| | 17 | | 7 | |
| | 18 | | 8 | |
| | 19 | | 9 | Vesicles (blisters) |
| | 20 | | 10 | |
| Contagious | 21 | | 11 | Pustules (pus-filled blisters) |
| | 22 | | 12 | |
| | 23 | | 13 | |
| | 24 | | 14 | |
| | 25 | | 15 | Scabs |
| Scabs contagious | 26 | | 16 | |
| | 27 | | 17 | |
| | 28 | | 18 | |
| | 29 | | 19 | |
| | 30 | | 20 | |
| Not contagious | 31 | | Scars | |
| | 32 | | | |

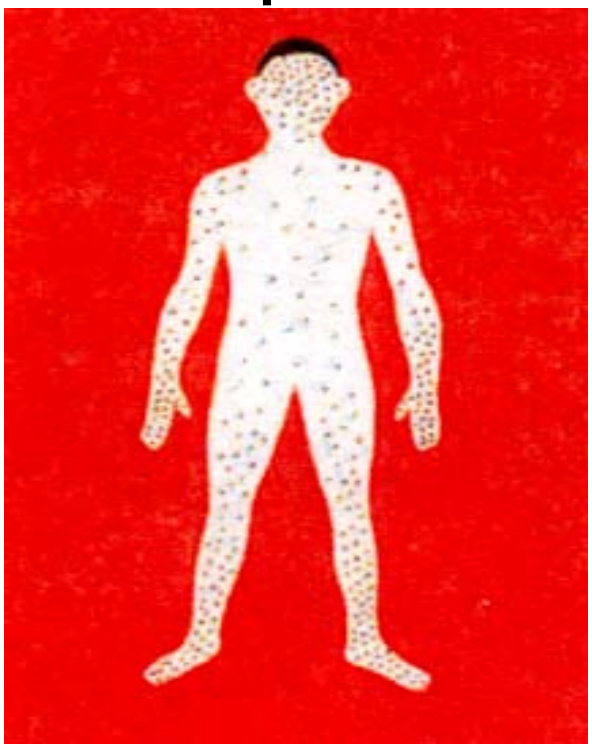
# Smallpox

# Diagnosis of Smallpox

- One case of smallpox must be treated as an international health emergency
- Characteristic rash:
  - Centrifugal in distribution
  - Most dense on face and extremities
- Smallpox was seldom suspected until more cases appeared and outbreak recognized
- Early cases: laboratory confirmed
- Later cases: clinical diagnosis

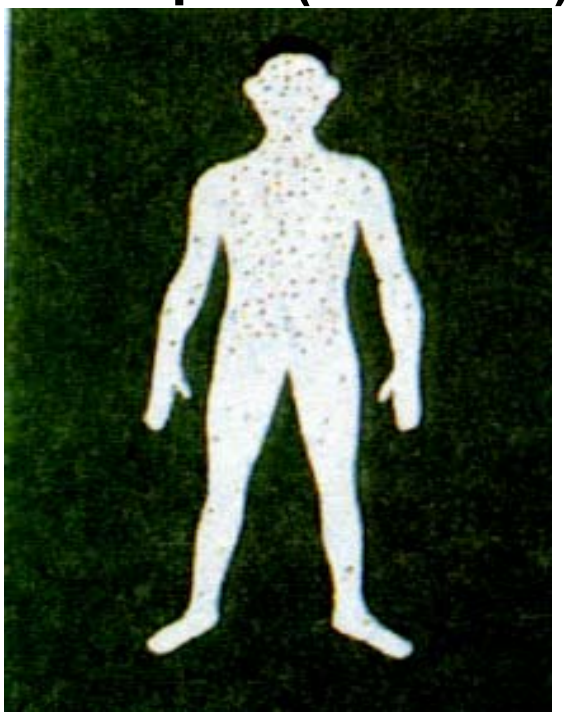
# Differential Diagnosis

## Smallpox



- Lesions appear in 1 to 2 day period
- On any part of body, lesions in same stage of development

## Chickenpox (Varicella)



- New lesions appear in crops every few days
- Lesions at different stages of maturation
- More lesions on trunk than face and extremities

# Care of Smallpox Patient

- Supportive therapy helps reduce fever, pain, etc. But no established treatment for smallpox
- Smallpox vaccination up to 3 days after someone is exposed to smallpox virus will prevent or reduce the severity of smallpox in most people
- Vaccination 4 to 7 days after exposure likely offers partial protection
- Cidofovir proposed to treat smallpox, but no human efficacy data

# Smallpox Vaccine in History

- 1776: Smallpox: US forces too weak to capture Quebec:
  - 5,500 smallpox casualties out of 10,000 forces
  - George Washington orders variolation of Continental Army against smallpox (archaic procedure, 2% fatal)
- 1796: Edward Jenner uses cowpox virus from milkmaid to prevent smallpox in a young boy
- 1812: War Dept orders Jennerian vaccine of US troops
- 1919: Citizens outraged that Woodrow Wilson permits smallpox vaccination of Armed Forces
- 1980: WHO declares Earth free of smallpox
- 1984: DoD restricts vaccination to recruits at basic training
  Policy intermittent: shortage of VIG, HIV testing begins
- 1990: DoD "temporarily discontinues" SMA vaccinations
- 2002: ~ 60% of AD personnel never vaccinated against smallpox; most of force is susceptible to infection

# Vaccine Effectiveness

***Smallpox vaccine prevents smallpox, but requires very careful use***

- **World Health Organization (WHO) used this vaccine to eradicate natural smallpox**
  - **95% of people are protected within 10 days**
  - **Solid protection lasts for 3 to 5 years**
  - **Partial protection lasts longer**
    - **But people need to be revaccinated, if too much time has passed (≥ 5 to 10 years)**
  - **Can protect up to 3 days after exposure**
- **Contains live vaccinia virus, cannot cause smallpox**
- **Same vaccine given since World War II**

# Smallpox Vaccine

***FDA recently licensed a supply of smallpox vaccine made by Wyeth Laboratories, called Dryvax®.***

- **The vaccine is made from virus called *vaccinia*, which is another "pox"-type virus related to smallpox**
- **The vaccine helps body develop immunity to smallpox**
- **Vaccine used for Service Members passes all tests required by Food and Drug Administration (FDA)**
- **Smallpox vaccine was first vaccine ever (1796) and has been used successfully for over 200 years**

# Exemptions to Vaccination

Medical exemptions are given for medical conditions that increase the risk of serious adverse events

- Some people should not get smallpox vaccine, except under emergency situations. A Medical Exemption is given IF:
  - Your immune system is not working fully (due to disease, medication, or radiation)
  - You have or had eczema or atopic dermatitis
    - Red, itchy, scaling rash lasting more than 2 weeks, comes & goes
  - You have active skin diseases, such as:
    - Burns, psoriasis, contact dermatitis, chickenpox, shingles, impetigo, uncontrolled acne, until it clears up or is under control
  - You are pregnant
  - You have a close contact with someone with the risk factors above ↑
  - You have a serious heart disease (such as angina, heart attack, congestive heart failure, other cardiac problem) or ≥ 3 risk factors
  - You use steroid eye drops or ointment or recovering from eye surgery
  - You are breastfeeding
  - You are allergic to smallpox vaccine or a component such as polymyxin B, streptomycin, tetracycline, neomycin, or latex

# Alternate Housing

- People who have household contact with person with bar to smallpox vaccination shall:
  - either have alternative housing arrangements
  - or be exempted from smallpox vaccination until household-contact situation no longer applies (i.e., scab falls off)

Unacceptable: Permitting vaccinated SM to reside in house, trailer, apartment, or similar close arrangements (e.g., "hot-bunking") with medically-barred contact

Acceptable:

- Vaccinated SM uses alternate lodging (e.g., barracks, dorm room, tents) on military installation, vessel, or aircraft, or in contracted space
- Berthing barges, familiar to naval forces in shipyards
- Vaccinated SM voluntarily arranges for alternate lodging in privately-owned or managed space is acceptable, if commander has reasonable expectation that SM will comply with requirement
- Schedule vaccinations shortly before or during 2- to 4-week deployments or family separation

# Pregnancy & Infant Care

- Defer smallpox vaccination until after pregnancy:
  - When pregnant women get smallpox vaccine, pregnancy usually goes well
  - In rare cases, vaccine virus caused vaccinia infection of the fetus
  - Smallpox Vaccine in Pregnancy Registry: Phone: 619.553.9255 E-mail: code25@nhrc.navy.mil
  - Avoid pregnancy for 4 weeks after vaccination
- In an outbreak, personal benefit from vaccination may outweigh risks
- Take care to prevent spread of vaccine virus to infants up to 1 year of age. ALWAYS wash hands before handling infant (e.g., feeding, changing diapers)
- Smallpox vaccine not recommended for nursing mother, as it could put infant in close contact with mother's vaccination site

# HIV Infection

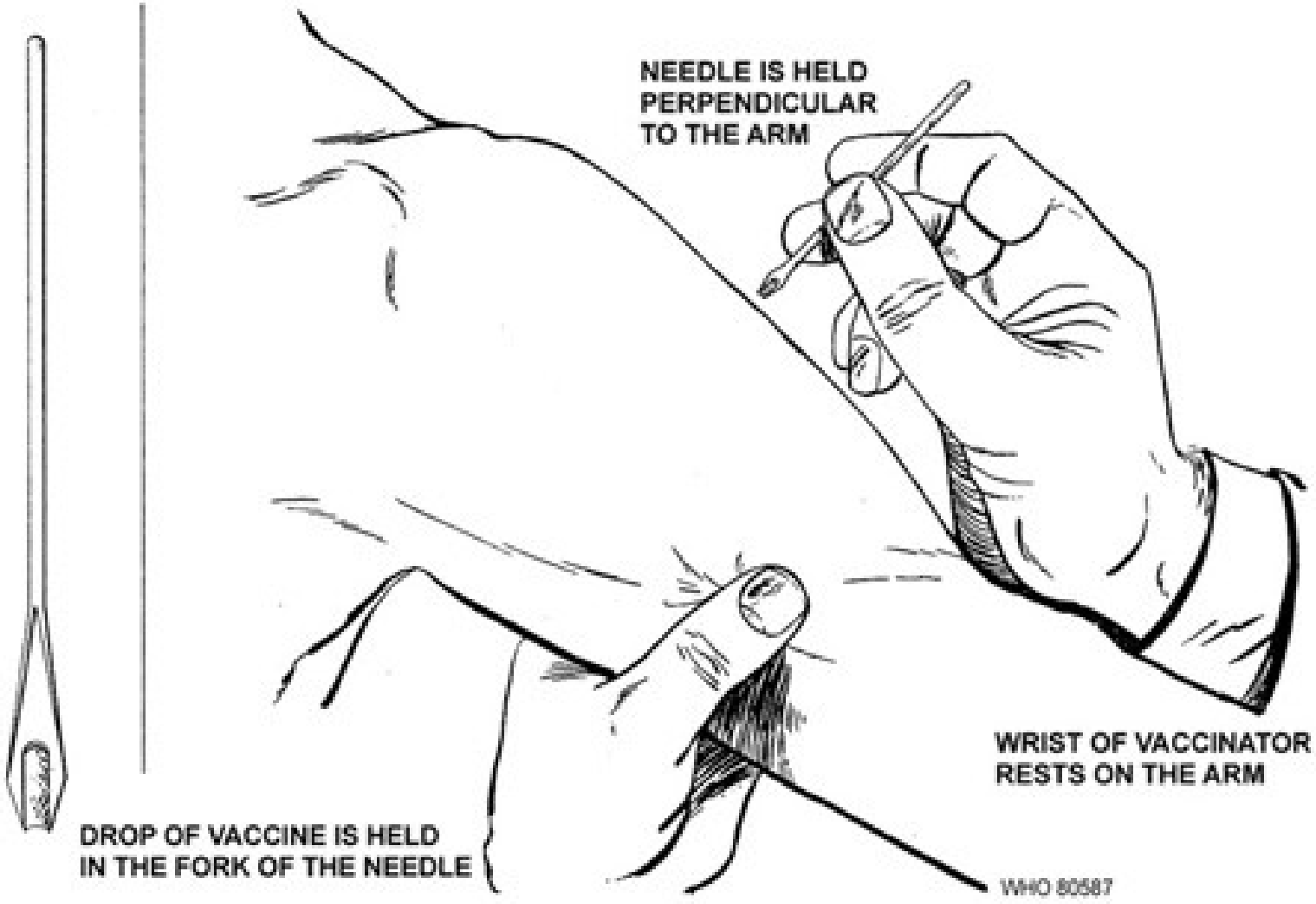
- HIV infection is a bar to smallpox vaccination
- Service Members must be up-to-date with Service HIV-screening policies before smallpox vaccination
- DoD civilian employees and contractors will be offered HIV testing in confidential setting, with results before vaccination
- HIV testing recommended for anyone with history of risk factor for HIV infection, especially since last HIV test, and not sure of HIV-infection status
- Because known risk factors cannot be identified for some people infected with HIV, people concerned they could be infected should be tested


CONTENTS: 100 STERILE NEEDLES
BIFURCATED VACCINATING NEEDLES
STERILE - SINGLE PATIENT USE ONLY
DO NOT RESTERILIZE
CAUTION: Federal law restricts this device to sale by or on the order of a physician.
Part Number: PB-01000-000-00
MANUFACTURED BY:
PRECISION MEDICAL PRODUCTS, INC.
DENVER, PA 17517 USA
www.pmp.net
TRIAL US

# Vaccination Technique

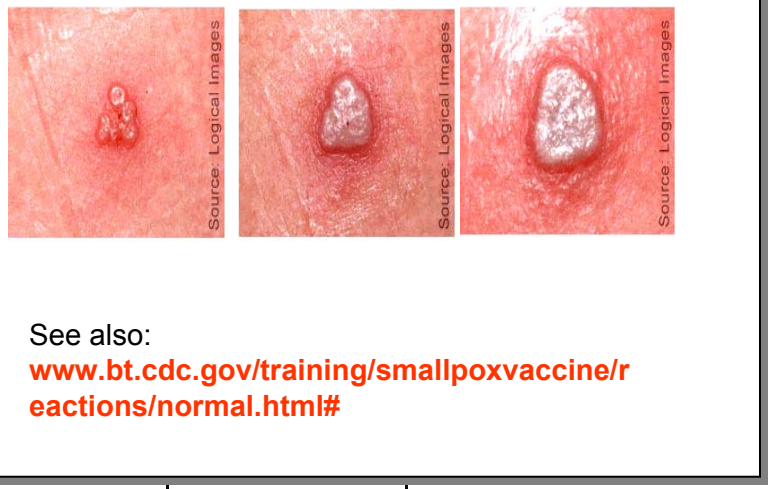
- Site: Skin over deltoid or posterior arm over triceps
- Cleanse site with soap & water, water only, then dry
- Use acetone or alcohol only if adequate time allowed to dry (or wipe site dry with gauze), to prevent inactivation
- Multiple-puncture technique uses bifurcated needle inserted vertically into the vaccine vial
- Primary (first) vaccination: 3 punctures, rapidly in 5 mm area, with strokes vigorous enough to cause a trace of blood after 15-20 seconds
- Revaccination: 15 punctures
- Evidence of prior smallpox vaccination (rough descending order of reliability):
  - medical documentation
  - characteristic Jennerian scar
  - entry into U.S. military service before 1984
  - birth in the United States before 1970

# Vaccination Technique



# *Successful Response to Vaccination*

| Day After Vaccination | Major Rxn, Primary (1st) | Major Reaction, for revaccinated | Equivocal: Delayed | Equivocal: All Other |
|---|---|---|---|---|
| Day 1 | | | Erythema | |
| 2 | | | Erythema ** | |
| 3 | Papule | Papule | No further rxn. | |
| 4 | (bump, pimple) | | | |
| 5 | Vesicle | Vesicle | | |
| 6 | (blister) | Pustule, induration | Requires | Requires |
| 7 | Pustule -- | or congestion | revaccination | revaccination |
| 8 | pus-filled blister | around | | |
| 9 | (center | scab or ulcer | | |
| 10 | (if previously | | | |
| 11 | vaccinated, may | | | |
| 12 | show 'induration' | | | |
| 13 | (hard swelling) | | | |
| 14 | | | | |
| 15 | Scab | | | |
| 16 | (dark, then | | | |
| 17 | flesh-colored) | | | |
| 18 | | * greatest erythema | | |
| 19 | | occurs after 3d day | | |
| 20 | Scab falls off | after revaccntn; | ** vesicles | |
| 21 | (day ~ 14 to 28) | viral propagation. | infrequently | |




See also:
**www.bt.cdc.gov/training/smallpoxvaccine/reactions/normal.html#**

# Symptoms Since Vaccination

Day 6-8, “Take Check,” symptoms after vaccination, n = 5,951, Jan-Apr 2003

| | | | |
|---|---|---|---|
| • Local itching | 62% | Muscle ache | 27% |
| • Feeling lousy | 26% | Lymph nodes swell | 23% |
| • Headache | 23% | Bandage reaction | 16% |
| • Itchy all over | 11% | Fever (subjective) | 6.6% |
| • Local rash | 11% | Body rash | 2.3% |
| • Restrict activity | 2.4% | Took medication | 5.0% |
| • Outpatient visit | 1.1% | Limited duty | 0.3% |
| • Missed work | 0.4% | Hospitalized | 0.1% |

# Revaccination (Two Kinds)

**Revaccination, no take:**

- **No take: Give 1 revaccination, 15 punctures (jabs)**
- **People previously vaccinated not responding with visible skin lesion after two attempts: Consider medically immune**
- **Refer others for immunologic evaluation, if having recurrent infections.**

**•Revaccination, booster interval:**

(preliminary recommendations)

- **Revaccinate if > 5 y elapsed after 1st vaccination**
- **Revaccinate if > 10 y elapsed after last vaccination**

# *Timing vis-à-vis Other Vaccines*

- **ACIP accepts administration of live and inactivated vaccines simultaneously or at any interval**
- **The only major restriction to combining vaccinations is with multiple live-virus vaccines**
  - **Either give simultaneously**
  - **or separated by 28 days or more**
- **Separate varicella (chickenpox) and smallpox (vaccinia) vaccinations by 28 days, to avoid confusing lesions**
- **Do not administer other vaccines near vaccination site**

# Side Effects—Serious

- In past, about 1,000 out of 1,000,000 people had reactions that were serious, but not life-threatening
  - Most involved vaccine virus elsewhere on body
  - Many preventable through better *hand washing!*
- 14 to 52 people out of 1,000,000 vaccinated for first time had potentially life-threatening reactions
  - 1 or 2 people of 1,000,000 may die as a result
- Serious side effects are generally more rare after revaccination but may require prolonged care
- To reduce risk of side effects, exempt people with immune problems or certain skin or heart conditions

# Serious Adverse Events

- **Serious reactions that may require medical attention:**
  - Accidental spread of virus elsewhere on body or to another
  - Widespread vaccine rash where sores break out away from vaccination site (generalized vaccinia)
  - Allergic rash after vaccination (erythema multiforme)
  - Inflammation of or around heart (myo-pericarditis)
- **Life-threatening reactions that need immediate attention:**
  - Serious skin rashes in people such as those with eczema or atopic dermatitis (eczema vaccinatum)
  - Ongoing infection of skin with tissue destruction (progressive vaccinia or vaccinia necrosum)
  - Postvaccinal encephalitis, inflammation of the brain
  - Chest pain or shortness of breath

# *Adverse Reactions*

- **See 16-panel CDC color brochure:**
  - ***Smallpox Vaccination: Methods & Reactions***

- **See also additional images at www.bt.cdc.gov/training/smallpoxvaccine/reactions**

# Care of Vaccination Site

*This woman touched her vaccination site, then touched her eye.*
*She recovered with a scarred eyelid.*

**Vaccine virus remains at the site, scab falls off & can infect others**

- Vaccine recipients need to be careful and informed
- Vaccine recipients need to educate close contacts about risk

1. **Don't touch any vaccination site**
2. **If you touch it by accident, wash your hands right away**
3. **Don't let others touch vaccination site or materials that covered it**
   - Wear gloves if assisting with site care
4. **Handle your own laundry/towels and place in hot soapy water**

# Hand Washing & Hand Hygiene

- Wash hands with soap and warm water
  - rub hands together vigorously **for at least 10 seconds**
  - cover all surfaces of the hands and fingers
  - rinse hands with warm water
  - dry hands thoroughly with a **paper towel**
  - use paper towel to **turn off the faucet**
- Alcohol-based waterless hand rinse, *e.g.,* CalStat®
  - Excellent alternative if hands are not visibly soiled
  - Apply product to palm and rub hands together, covering all surfaces of hands and fingers, until hands are dry
  - May have sticky feel after repeated use – wash hands with soap and water as needed

# Hand Washing & Hand Hygiene

To prevent accidental virus exposure to the genital or rectal area, wash your hands **BEFORE** using the bathroom.

After using the toilet,
**Wash your hands again**

**Be extremely careful with your contact lenses!**

- Wash hands thoroughly before you touch your eye or the lenses
- Wearing your glasses until site heals is preferred

# Care of Vaccination Site

Follow these instructions carefully, or you could harm yourself or others. Ask questions if anything is unclear.

- **Until your scab falls off**, avoid spreading vaccine virus to close contacts, particularly with people exempted from getting vaccinated
- **Do not share a bed, bunk, or cot with people who are exempted from vaccination**
  - You can spread vaccine virus to anyone, so **Wash Your Hands**
- Do not share clothes, towels, linen, or toiletries
  - You can spread vaccine virus to anyone, so **Wash Your Hands**

# Care of Vaccination Site

Follow these instructions carefully, or you could harm yourself or others. Ask questions if anything is unclear.

- **Wear sleeves to cover the site**.
- Wear sleeves at night, if you sleep in bed with someone.
- **Use bandages**. Change them every few days.
- Discard bandages in sealed or double plastic bags. You may carefully add bleach, alcohol, or soap, if desired
- **Keep site dry.** Bathe normally, but dry the site last, with something disposable. Avoid rubbing. Avoid swimming or public bathing facilities
- **Launder** clothing, towels, and sheets in hot water with detergent or bleach.
- When the scab falls off, flush it down the toilet. Soap, alcohol, sunlight, chlorine, and bleach kill the virus.
- **Wash your hands – Hand washing, hand washing!**

# Extra Cautions for Healthcare Workers

- Minimize contact with unvaccinated patients until scab falls off
- If contact essential and unavoidable, workers can continue to work with patients, including those with immunodeficiencies:
  - If site well-covered and thorough hand-hygiene maintained
  - Semi-permeable bandage (Opsite, Tegaderm, Cosmopore)
- To prevent accumulation of exudates, cover site with dry gauze, and then apply dressing over gauze
- Change dressing daily or every few days (according to type of bandaging and amount of exudate), eg, start or end of shift.
- Site-care stations: to monitor worker vaccination sites, promote effective bandaging, and encourage scrupulous hand hygiene
- Long-sleeve clothing further reduces risk for contact transfer
- Most critical measure: Thorough hand-hygiene after changing bandage or any contact with site

# Treatment of Adverse Events

- Be alert for serious, rare, adverse events after vaccination
- Consult as appropriate with allergy-immunology, infectious-disease, dermatology, neurology, or specialist(s).
- Some conditions respond to vaccinia immune globulin (VIG)
    - Eczema vaccinatum, progressive vaccinia, severe ocular vaccinia, severe generalized vaccinia
    - VIG not effective in treating post-vaccinial encephalitis
- VIG consists of human IgG antibody from people vaccinated with smallpox vaccine
- VIG available under IND protocol, by calling USAMRIID at 1-888-USA-RIID or 301-619-2257

# Documentation

- Screening: Record contraindications in medical record
- Vaccination: Individual medical records + computer
- Confirmation of successful vaccination:
  - Instruct all: Come back to clinic, if no characteristic lesion
  - Healthcare workers and response team members (traveling into smallpox outbreak area) will have “take” recorded in their health records
  - Other personnel should have vaccination take recorded in health records by medic or provider trained in vaccination evaluation
- Adverse events:
  - Medical records, VAERS, VHC access
- USD(P&R): Services will audit immunization tracking systems

# Adverse Event Reporting

- Vaccine Adverse Event Reporting System (VAERS)
  - FDA and CDC review 100% of reports submitted
  - Anyone can submit a VAERS form, online preferred https://secure.vaers.org
  - Reporting with medical help results in more detail
- DoD requires a VAERS form for:
  - Loss of duty 24 hours or longer (≥ 1 duty day)
  - Hospitalization
  - Suspected vaccine vial contamination
  - Auto-inoculation or contact vaccinia
- Other submissions encouraged
- Report to VAERS at www.vaers.org or call 800-822-7967

# Reserve Adverse-Event Care

- Adverse events after DoD- or USCG-directed vaccinations are line-of-duty conditions
- Someone with an adverse event in a non-duty status possibly associated to any vaccination:
  - Seek medical evaluation at a DoD, USCG, or civilian medical treatment facility, if necessary
  - Must report the event to your unit commander or designated representative as soon as possible
  - See local medical department or squadron for guidance
- Commander will determine Line of Duty and/or Notice of Eligibility status, if required

# Vaccines

*Preserving the health and safety of our people are our top concerns*

- **Vaccines will keep you and your team healthy**
- **Healthy troops complete their missions**
- **Vaccines:**
  - **Shield you from dangerous germs**
  - **Keep units fit to fight**
  - **Help you return home safely**
- **Vaccines saved more lives than any other medical invention, more than antibiotics or surgery. Only clean water has saved more lives**

# Vaccine Safety

- Carefully read & complete screening form
  - You are helping accurately document that it is safe to give you the vaccine
- Ask questions if you are unsure
- Contact family members who may know about childhood history of recurrent rashes like eczema
- Talk to close contacts and family members about the vaccination program and safety precautions
- Ask for assistance at any point, if needed by you or your close contacts or if you have safety concerns

# *Information Sources*

- Chain of Command
- Website: www.smallpox.mil; www.anthrax.mil
- E-Mail: vaccines@amedd.army.mil
- Toll-Free: 877.GET.VACC
- DoD Vaccine Clinical Call Center: 866.210.6469
- DoD Vaccine Healthcare Centers, for help with complicated adverse-event management: 202.782.0411
  - Askvhc@amedd.army.mil www.vhcinfo.org
- Information for Civilian Healthcare Providers: Call the Military Treatment Facility (MTF) where the member is enrolled –OR– contact the Military Medical Support Office (MMSO) 888.647.6676 if the member is not enrolled to an MTF.
- Smallpox Vaccine in Pregnancy Registry, 619.553.9255
  - code25@nhrc.navy.mil